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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,015	01/28/2002	Bernd H. Meier	VON KREISLER.015	8627
110	7590	04/20/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,015

Applicant(s)

MEIER ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) 1-53 and 78-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-62, 67-69, 74 and 75 is/are rejected.
- 7) ☒ Claim(s) 63-66 and 70-73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of the preliminary amendment filed 08/21/2003.

Election/Restrictions

Applicant's election without traverse of Group IV in Paper No. 12192003 is acknowledged.

Claims 1-~~57~~³, 78-112 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12192003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite in that the metes and bounds of the claimed colloid-forming Markush Group are not particularly set out since the group includes "modified" polysaccharides and polypeptides. Clarification is requested.

Claim 54 is also indefinite in that the Markush group of bioactives contains "Parkinsons remedies and other remedies against extrapyramidal disturbances". These

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other remedies make the metes and bounds of the claimed Markush group indefinite.

Clarification is requested.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP2304023 (JP'023).

JP'023 disclose the combination of lysine and a colloid forming macromolecule. Specifically, hydroxyethyl starch and dextran are recited (see Abstract). The molecular weight of hydroxyethyl starch is listed as between 40000 and 400,000. The molecular weight of dextran is recited as between 7000 and 40000. Given that the claimed hydrocolloids are used for the same art recognized purpose, and fall within the same molecular weight range, the degree of substitution for each is considered inherent to the composition as claimed. The instant claims are therefore anticipated by JP'023.

Claims 54-55, 68, 69, and 75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP 0 193 917 (EP'917).

EP'917 disclose a composition for parenteral administration which includes growth hormones as well as water soluble carbohydrate polymers including detrans, starches, and cellulose (see abstract; page 3, lines 9-11). These polymers are chosen

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for their colloidal characteristics (see page 3, line 23). Since applicant is using the same polymers, for the same art recognized colloidal properties, the colloid osmotic pressure is an inherent property of the solutions utilizing said polymers. The instant claims are clearly anticipated by EP'917.

Claims 54, 55, 67, and 74 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by FR 2 296 429 (FR'429).

FR'429 an injectable composition comprising immunoglobulins Page 1, lines 1-30. This is done in the presence of hydrocolloids as listed at page 2, lines 23-25. These include gelatin, dextran, albumin, and polyols. The instant claims are clearly anticipated.

Claims 63-66, 70-73, and 76 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0602. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

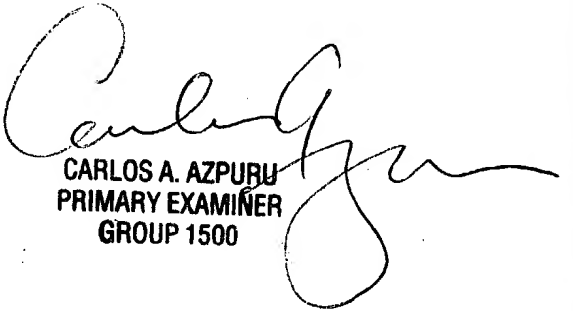
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0588. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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